4.0 510(k) Summary - K102176

SEP 1 2010

Submitter:	Medtronic CryoCath LP 16771 Chemin Ste-Marie Kirkland, Quebec H9H 5H3, CANADA
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Date Prepared:	August 2, 2010 - *Revised August 31, 2010*
Trade Name:	FlexCath® Steerable Sheath & Dilator
Classification:	Class II Steerable Catheter, 21 CFR § 870.1280
Product Code:	DRA
Predicate Device(s):	The subject device is equivalent to the following devices: • K081049 - FlexCath Steerable Sheath & Dilator, Models 3FC10, 3FC12
Device Description:	The FlexCath Steerable Sheath is a deflectable catheter introducer used to facilitate placement of a catheter through the skin into the artery or vein. It is comprised of the following two (2) main sections: the shaft and the handle. A dilator is included with each sheath. This application addresses changes to the 12F FlexCath sheath tip and valve assembly.
Intended Use:	The FlexCath Steerable Sheath is intended for percutaneous catheter introduction into the vasculature and into the chambers of the heart. The sheath deflection facilitates catheter positioning.
Functional and Safety Testing:	To verify that the modified device design met its functional and performance requirements, representative finished sterilized samples of the subject device underwent the following in vivo, ex vivo animal testing, biocompatibility and mechanical testing in accordance with applicable industry standards and FDA guidance. Testing included: • Hemostasis valve leak testing (per ISO 11070) • Hub-to shaft tensile (per ISO 11070) • Shaft leak testing (per ISO 11070)

- Assessment of the force required to detach the dilator luer lock from the sheath valve cap
- Force required to remove the dilator from the sheath
- Tensile testing of bond joints (in addition to those required by ISO 11070) including:
    - valve hub to valve cap
    - hub body to extension
    - tube bond and stopcock to extension tube joints
- Sheath tip robustness testing after multiple catheter deployments/retractions, both in bench and animal models
- Air aspiration and flushing ability
- Tip Strength
- Deflection testing
- Assessed impact of changes in relation to current sterilization cycle in accordance with AAMI TIR28:2001.

Biocompatibility Testing:

Biocompatibility of the modified hub material for the subject device included:

- Physiochemical testing USP 33 <661>
- Cytotoxicity testing per ISO 10993-5 (2009)
- Hemolysis testing (human activated and indirect) per ISO 10993-4 (2002 Amd 2006)

Leveraged biocompatibility of the predicate device included:

- Kligman Maximization Test per ISO 10993-10 (2002)
- Rabbit Pyrogen Test – Material Meditated per ISO 10993-11 (2006)
- Intracutaneous Test per ISO 10993-10 (2002)
- Systemic Injection Test per ISO 10993-11 (2006)
- Complement Activation Assay per ISO 10993-4 (2002)

- UPTT per ISO 10993-4 (2002)
- Thrombogenicity In vivo canine per ISO 10993-4 (2002)

Conclusion: The changes to the subject FlexCath Steerable Sheath do not affect the intended use of the device, do not alter the fundamental scientific technology of the device, or raise new issues of safety or effectiveness. The FlexCath Steerable Sheath is therefore substantially equivalent to the predicate FlexCath Steerable Sheath.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Medtronic CyroCath LP
c/o Ms. Kari Lahti
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SEP 1 2010

Re: K102176
Trade/Device Name: FlexCath® Steerable Sheath & Dilator
Common Name: Steerable Catheter
Regulation Number: 21 CFR 870.1280
Regulatory Class: II
Product Code: DRA
Dated: August 2, 2010
Received: August 3, 2010

Dear Ms. Lahti:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K102176

3.0 Indications for Use Statement

510(k) Number (if known): K 102176

Device Name: FlexCath® Steerable Sheath and Dilator

Indications for Use:

The FlexCath Steerable Sheath is intended for percutaneous catheter introduction into the vasculature and into the chambers of the heart. The Sheath deflection facilitates catheter positioning.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K102176